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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,128	02/04/2002	Joel Krasnow	3414/1	6002

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EXAMINER	
BAHAR, MOJDEH	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 08/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/067,128	Applicant(s) KRASNOW, JOEL	
	Examiner Mojdeh Bahar	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) *7-21, 23-24, 26-33, 35-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,22,25 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's amendment and remarks submitted April 28, 2003 are acknowledged. Applicant's confirmation of the election of the invention of Group I and celecoxib and ethinyl estradiolas the elected species is acknowledged.

Claims 7-21, 23-24, 26-33 and 35-55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions/species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.

Claims 1-6, 22, 25, and 34 are herein examined on the merits in so far as they read on the elected species.

The restriction/election requirement is still deemed proper and is made FINAL.

This application contains claims 7-21, 23-24, 26-33 and 35-55 drawn to an invention nonelected without traverse in Paper No. 9. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The Information Disclosure Statement of July 1, 2002 has not been considered, since the references were not found in the office. Note that applicant has submitted a new PTO-1449, but none of the references are submitted therewith.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Deligeorglou.

Deligeorglou teaches the employment of a pharmaceutical composition comprising oral contraceptives in a method of treating dysmenorrhea. Deligeorglou further discloses that if good relief of dysmenorrhea is not achieved with oral contraceptives alone, a prostaglandin inhibitor can be added. Deligeorglou specifically teaches the employment of cyclooxygenase inhibitors in treating dysmenorrhea, see particularly *Management* on page 241.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 22, 25 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deligeorglou (*Dysmenorrhea*. Ann. N Y Acad. Sci. 2000; 900:237-44) in view of PDR (50th Ed., 1996) and Harrison et al. (USPN 6,086,909).

Deligeorglou teaches the employment of a pharmaceutical composition comprising oral contraceptives in a method of treating dysmenorrhea. Deligeorglou further discloses that if good relief of dysmenorrhea is not achieved with oral contraceptives alone, a prostaglandin inhibitor can be added. Deligeorglou specifically teaches the employment of cyclooxygenase inhibitors in treating dysmenorrhea, see particularly *Management* on page 241.

Deligeorglou does not particularly teach the employment of ethinyl estradiol and celecoxib in its method of treating dysmenorrhea. Neither does it teach the incorporation of ethinyl estradiol and celecoxib in a single composition.

PDR (50th Ed., 1996) teaches that the administration of a pharmaceutical composition comprising ethinyl estradiol diminishes pain during menstruation and reduces the incidence of dysmenorrhea, see in particular pages 2090 and 2093.

Harrison et al. (USPN 6,086,909) teaches a pharmaceutical composition comprising non-estroidal anti-inflammatory drugs such as celecoxib suitable for employment in a method of treating dysmenorrhea, see in particular col.2, lines 18-36 and abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ ethinyl estradiol and celecoxib in a combination composition.

One of ordinary skill in the art would have been motivated to employ ethinyl estradiol and celecoxib in a combination composition because the prior art teaches the employment of both classes of pharmaceuticals, i.e., oral contraceptives and COX inhibitors, in a method of

treating dysmenorrhea. Furthermore, each of the actives is individually known to be useful in a method of treating dysmenorrhea. Combining two agents which are known to be useful to treat dysmenorrhea individually into a single composition useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069.

Response to Arguments

Applicant's arguments filed April 29, 2003 have been fully considered but they are not persuasive. Applicant first argues that the Deligeorglou reference does not teach a COX-2 inhibitor. Note that it is well known in the art that COX inhibitors, inhibit both COX-1 and COX-2 isoforms, see page 692 last paragraph of the first column to the end of the first paragraph of the second column, pages 690-692 of *Goodman and Gilman*. Therefore a known COX inhibitor would indeed inhibit COX-2 and would meet the claimed limitation of "a COX-2 inhibitor compound source." Given that the prior art reference teaches a method of treating dysmenorrhea employing a combination of contraceptives and a COX inhibitor the claimed limitations are met and a 102 rejection is proper.

Applicant then argues that a prima facie case of obviousness has not been established. Applicant refers to the Court's reasoning in *In re Geiger*, 2 USPQ2d 1277, (Fed. Cir. 1987). Note that this case is distinguishable from *Geiger* because the Court's reasoning in *Geiger* was based on the non-analogous nature of the prior art. Here the cited prior art is indeed analogous and therefore the analysis of Geiger does not apply. Moreover, note that the prior art specifically teaches the employment of a pharmaceutical composition comprising oral contraceptives in a method of treating dysmenorrhea. It further discloses that if good relief of dysmenorrhea is not achieved with oral contraceptives alone, a prostaglandin inhibitor can be added. Deligeorglou

specifically teaches the employment of cyclooxygenase inhibitors in treating dysmenorrhea, see particularly *Management* on page 241. Therefore the cited prior art teaches the employment of the two agents herein in a method of treating dysmenorrheal.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 on Monday, Tuesday, Thursday and Friday from 8:30 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
August 18, 2003

SREENI PADMANABHAN
PRIMARY EXAMINER

8/21/03